Goal 3: Safe Food

The foods Americans eat will be free from unsafe pesticide residues. Particular attention will be given to protecting subpopulations that may be more susceptible to adverse effects of pesticides or have higher dietary exposures to pesticide residues. These include children and people whose diets include large amounts of noncommercial foods.

Background and Context

The U.S. Environmental Protection Agency (EPA) plays a major role in the lives of the American public by ensuring that agricultural use of pesticides will not result in unsafe food. EPA accomplishes this by registering new pesticide products and reviewing older pesticide products by strict standards that protect human health and the environment from risks associated with pesticide use.

EPA uses the latest scientific information to ensure that there is "a reasonable certainty" that no harm will result to human health from all combined sources of exposure to pesticides (aggregate exposures). Moreover, it submits for review its pesticide regulations and related science issues to the Science Advisory Panel (SAP), an independent, expert advisory committee whose members are nominated by the National Institutes of Health and the National Academy of Sciences. The SAP plays a critical role in EPA's decision-making process, assuring decisions that impact on health and the environment rely on sound science.

The potential risk of adverse effects to consumers from pesticide residues in foods is a primary concern for the Agency, as is the potential bioconcentration of certain pesticides in plant and animal tissues which may result in even higher levels of exposure. Critical to protecting human health is the review of food use pesticides for potential toxic effects such as birth defects, cancer, disruption of the endocrine system, changes in fertility, harmful effects to the kidneys and liver, and nervous system bioaccumulation. Under the Safe Food goal, EPA ensures that any residues on food are below established limits.

All pesticides are subject to EPA regulation including insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators, plant incorporated protectants and other substances intended to control pests. Pesticides are used in agriculture, greenhouses, on lawns, in swimming pools, industrial buildings, households, and in hospitals and food service establishments. The total U.S. pesticide usage in 1997 was 4.6 billion pounds, according to the report, "*Pesticide Industry Sales and Usage: 1996 and 1997*" (http://www.epa.gov/oppbead1/pestsales). Agriculture accounts for about 80 percent of all pesticide applications. Herbicides are the most widely used pesticides and account for the greatest expenditure and volume, approximately $6.6 billion and 568 million pounds in 1997. Biopesticides and reduced risk pesticides are assuming an increasingly important role. For example, safer pesticides, which include biopesticides and reduced risk pesticides, increased in use from 3.6% in 1998 to 7.1% of total pounds applied in 2000 (Doane Marketing Research, Inc.: http://www.doanemr.com).

EPA's Pesticide Regulations Affect a Cross Section of the U.S. Population

- 30 major pesticide producers and another 100 smaller producers
- 2500 formulators
- 29,000 distributors and other establishments
- 40,000 commercial pest control firms
- 1.2 million pesticide applicators
- One million farms
- Several million industry and government users
- About 100 million households

Source: OPP's Pesticides Industry Sales and Usage Report

EPA regulates pesticides under two main statutes: the Federal Insecticide, Fungicide and

Rodenticide Act (FIFRA) and the Federal Food and Drug Cosmetic Act (FFDCA). FIFRA requires that pesticides be registered (licensed) by EPA before they may be sold or distributed in the United States, and that they perform their intended functions without causing unreasonable adverse effects to people or the environment when used according to EPA-approved label directions.

FFDCA authorizes EPA to set tolerances, or maximum legal limits, for pesticide residues in or on food. Tolerance requirements apply equally to domestically-produced as well as imported food. Any food with residues not covered by a tolerance, or in amounts that exceed an established tolerance, may not be legally marketed in the United States.

Amendments to both FIFRA and FFDCA by the Food Quality Protection Act (FQPA) of 1996 enhances protection of children and other sensitive sub-populations. FQPA establishes a single, health-based safety standard for all pesticide residues. The agency-wide FY 2003 request supporting FQPA includes $142.3 million for EPA's work under these laws, enabling the public to enjoy one of the safest, most abundant, and most affordable food supplies in the world. FQPA also enhanced EPA's ability to protect human health and the environment in several other ways, including:

- Providing for a more complete assessment of potential risks, with special protections for sensitive groups, such as infants and children;
- Ensuring that pesticides are periodically reassessed for consistency with current safety standards and the latest scientific and technological knowledge;
- Educating consumers about pesticide risks and benefits;
- Expediting the approval of reduced risk pesticides; and
- Encouraging farmers' adoption of safer pest management practices.

Means and Strategy

The Agency's strategy for accomplishing the objectives of Safe Food is based on five pillars, four of which are in Goal 3 and one in Goal 4. Under Goal 3, the EPA is:

- Assuring that new chemicals and new uses are registered in accordance with the FQPA's strict standard, "reasonable certainty of no harm,"and that no harm will result to human health from all combined sources of exposure to pesticides (aggregate exposures);
- Assuring that pesticide maximum legally allowable tolerances for foods eaten by children are in conformance with FQPA requirements that protect children;
- Re-evaluating older, potentially higher-risk pesticides using the best current scientific data and methods to determine whether additional limits on a pesticide's use are needed to provide reasonable certainty of no harm, especially for children and other sensitive populations; and
- Expediting review and registration of alternative pesticides that are less risky than pesticides currently in use and may be substituted effectively for higher risk pesticides.

In 2003, the Agency will continue to promote accelerated registrations for pesticides that provide improved risk reduction or risk prevention compared to those currently on the market. Progressively replacing older, higher-risk pesticides is one of the most effective methods for curtailing adverse impact on health and the ecosystem while preserving food production rates.

EPA uses its authorities to manage systematically the risks of pesticide exposures by establishing legally permissible food-borne pesticide residue levels, or tolerances. EPA defines the legal use of pesticides, up to and including the elimination of pesticides that present a danger to human health and the environment. This task involves a comprehensive

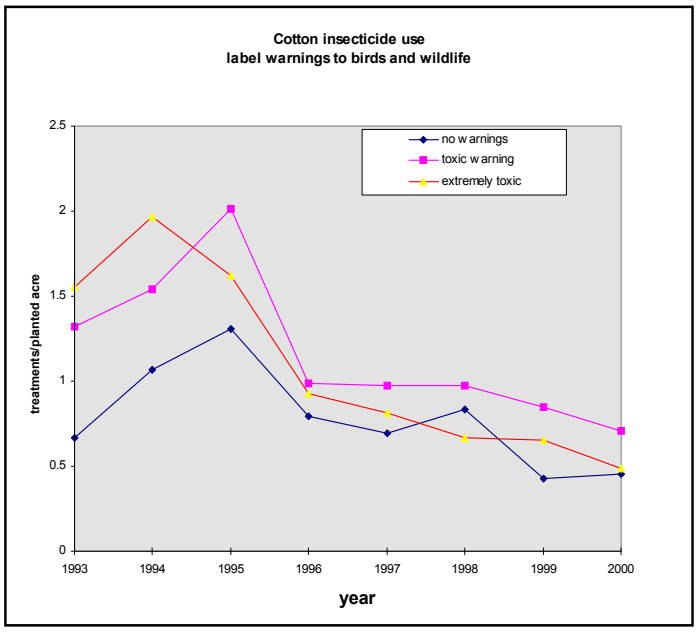
review of existing pesticide use as stipulated by the reregistration provision, as well as a comprehensive reassessment and update of existing tolerances within ten years, as required by FQPA.

The 2003 request emphasizes efforts to evaluate existing tolerances for currently registered pesticides to ensure they meet the new Food Quality Protection Act (FQPA) health standards. This tolerance reassessment program screens and requires testing of certain pesticides and chemicals to evaluate their potential for disrupting endocrine systems in animals or in humans. The emphasis will be on balancing the need for pesticides with the risks of exposure and allowing for smooth transitions to safer pesticide alternatives, through an open and transparent process that seeks input from all stakeholders.

EPA uses the latest scientific advances in health-risk assessment practices, to ensure that current pesticides meet the standard of a reasonable certainty of no harm, as stipulated by FQPA. This includes the incorporation of new scientific data relating to the effects of endocrine disruption and the special needs of susceptible populations such as children and Native Americans.

Adoption of biotechnology has great potential to reduce reliance on some older, more risky chemical pesticides, and to lower worker risks. For example, the use of Bt cotton has affected the use of other insecticides which present higher risk to wildlife. According to the reported number of insecticide treatments per planted acre of cotton, use of insecticides labeled either toxic or extremely toxic to wildlife has undergone significant reduction since 1995, the extremely toxic pesticides decreasing from 1.6 to 0.5 acre treatments, a 68% reduction. (See chart.)

Outreach activities on the subject of biotechnology such as public meetings and scientific peer reviews of our policies and assessments are likely to be expanded to keep pace with changing science and the public's demand for information in this area. EPA is working closely with other federal agencies involved in biotechnology and is also actively involved in developing international standards for the regulation of biotechnology products. Specific activities in 2003 will include advancing scientific knowledge of allergenicity (i.e.human allergic reactions to pesticide residues); continued implementation of the Plant Incorporated



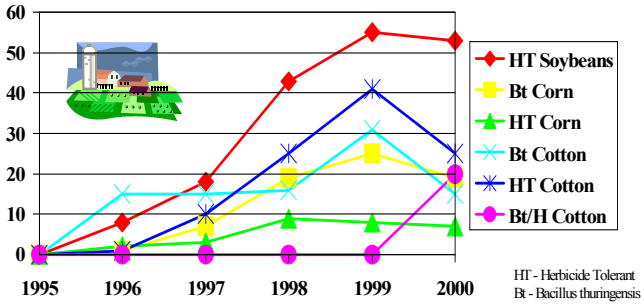
Protectant rule, which defines the type of substances used in bioengineered plants that must undergo scientific evaluation by the Agency; and participating in the Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology. The Task force is involved in developing international standards governing foods derived from biotechnology.

Use of biotechnology to modify plants so that they resist harmful insects or the effects of herbicides is likely to attract continued public scrutiny, particularly on issues such as allergenicity and gene transfer. Biotechnology is becoming increasingly more important in our economy with bioengineered plants accounting for a larger share of acres planted than ever before in the United States. For example, in 1996, Herbicide Resistant (HT) Soybeans accounted for only 8% of the total U.S. acres planted in soybeans. In 2000, HT Soybeans accounted for 53% of the acres planted for other crops, trends also indicate increases, though not as dramatically as for soy (see chart).

While certain issues remain to be addressed, among the potential benefits of biotechnology is a reduction of our reliance on some older, more risky

Adoption of Genetically Modified Plant Incorporated Protectant Crops

United States, 1995 - 2000 (percent of acres)



Source: Based on Data from ERS/NASS Survey

chemical pesticides, thereby reducing worker exposure to these chemical pesticides. To ensure the safety of foods derived from biotechnology, EPA will continue to seek outside expert scientific advice through scientific peer reviews on our regulatory decisions, policies, methods and tools.

New registration actions result in more pesticides on the market that meet the strict FQPA pesticide risk-based standards, which brings the Agency closer to the objective of reducing adverse risks from pesticide use. Tolerance reassessments may mean mandatory use changes because a revision in the allowable residue levels can involve changes in pesticide application patterns, changes in the foods the pesticides may be applied to, and other risk management methods. As measured by the number of tolerances that have been reassessed, the Agency's progress in the tolerance reassessment program directly serves the objective of reducing the use on food of pesticides that do not meet the new standards.

In addition to setting the requirements for continued legal use of agricultural pesticides, EPA works in partnership with USDA, FDA and the states toward the broader effort to prevent the misuse of pesticides. In the ever changing environment of pesticide use, accessibility to information is a primary component of an effective strategy to inform the public on the appropriate, safe use of pesticides to minimize risk.

More information about EPA's food safety efforts is available on the Agency's website at http://www.epa.gov/pesticides.

Research

Current approaches to human health risk assessment focus on single pesticides and do not adequately account for cumulative risks arising from complex exposure patterns and human variability due to age, gender, pre-existing disease, health and nutritional status, and genetic predisposition. Existing tools for controlling and preventing exposure are limited to certain processes and materials.

To support the Food Quality Protection Act (FQPA), EPA must develop the tools (methods, models, approaches) and quality exposure data for characterizing aggregate risks from exposure to pesticides in order to reduce uncertainty in risk assessments. The FQPA identifies clear science needs, including the evaluation of all potential routes and pathways of exposures to pesticides, and resulting health effects, particularly for sensitive subpopulations and considering effects from cumulative exposures.

EPA's research program will continue to focus on: 1) developing and validating methods to identify and characterize, as well as models to predict, the potential increased susceptibility to human health effects experienced by infants and children; 2) identifying and understanding major exposure routes, pathways, and processes, and developing theoretical and experimentally based multipathway exposure models for pesticides and other toxic substances; and 3) addressing the adequacy of current risk assessment methods and providing the necessary risk assessment guidance.

External Factors

The ability of the Agency to achieve its strategic objectives depends on several factors over which the Agency has only partial control or little influence. EPA relies heavily on partnerships with states, Tribes, local governments and regulated parties

to protect the nation's food supply, the environment, and human health, from pesticides.

EPA assures the safe use of pesticides in coordination with the USDA and FDA, who have responsibility to monitor and control residues on food and other environmental exposures. EPA also works with these agencies to coordinate with other countries and international organizations with which the United States shares pesticide-related environmental goals. This plan discusses the mechanisms and programs the Agency employs to assure that our partners will have the capacity to conduct the activities needed to achieve the objectives. Much of the success of EPA's pesticide programs also depends on the voluntary cooperation of the private sector and the public.

Other factors that may delay or prevent the Agency's achievement of the objectives include lawsuits that delay or stop the planned activities of EPA and/or state partners, new or amended legislation and new commitments within the Administration. Economic growth and changes in producer and consumer behavior could also have an influence on the Agency's ability to achieve the objectives within the time frame specified.

Large-scale accidental releases, such as pesticide spills, or rare catastrophic natural events (such as hurricanes or large-scale flooding), could impact EPA's ability to achieve objectives in the
short term. In the longer term, the time frame for achieving many of the objectives could be affected by new technology or unanticipated complexity or magnitude of pesticide-related problems.

Newly identified environmental problems and priorities could have a similar effect on long-term goals. For example, pesticide use is affected by unanticipated outbreaks of pest infestations and/or disease factors, which require EPA to review emergency uses in order to preclude unreasonable risks to the environment. While the Agency can provide incentives for the submission of registration actions such as reduced risk and minor uses, EPA does not control incoming requests for registration actions. As a result, the Agency's projection of regulatory workload is subject to change.

Resource Summary

(Dollars in Thousands)

	FY 2001 Actuals	FY 2002 Enacted	FY 2003 Request
Safe Food	**$124,949.3**	**$109,071.7**	**$109,814.6**
Reduce Risks from Pesticide Residues in Food	**$44,288.8**	**$47,609.6**	**$45,290.4**
Environmental Program & Management	$37,994.5	$45,325.3	$42,964.7
Rereg. & Exped. Proc. Rev Fund	$3,790.4	$0.0	$0.0
Science & Technology	$2,503.9	$2,284.3	$2,325.7
Eliminate Use on Food of Pesticides Not Meeting Standards	**$80,660.5**	**$62,927.5**	**$64,524.2**
Environmental Program & Management	$58,202.0	$50,344.6	$52,478.3
Rereg. & Exped. Proc. Rev Fund	$12,857.8	$0.0	$0.0
Science & Technology	$9,601.6	$12,582.9	$12,045.9
Total Workyears	**817.1**	**777.5**	**770.1**

Objective 1: Reduce Risks From Pesticide Residues in Food

By 2006, reduce public health risk from pesticide residues in food from pre-Food Quality Protection Act (FQPA) levels (pre-1996).

Key Program

(Dollars in Thousands)

	FY 2001 Enacted	FY 2002 Enacted	FY 2003 Request	FY 2003 Req. v. FY 2002 Ena.
Administrative Services	$209.7	$0.0	$0.0	$0.0
Endocrine Disruptor Screening Program	$2,279.9	$1,860.4	$2,096.3	$235.9
Facilities Infrastructure and Operations	$4,250.0	$4,725.2	$4,462.6	($262.6)
Homeland Security	$0.0	$602.6	$0.0	($602.6)
Legal Services	$996.7	$1,019.7	$1,095.3	$75.6
Management Services and Stewardship	$460.2	$504.0	$420.6	($83.4)
Pesticide Registration	$29,613.9	$31,832.4	$30,882.2	($950.2)
Pesticide Reregistration	$5,371.5	$6,227.0	$5,673.4	($553.6)
Pesticide Residue Tolerance Reassessments	$1,177.4	$813.3	$660.0	($153.3)
Safe Pesticide Applications	$0.0	$25.0	$0.0	($25.0)

Annual Performance Goals and Measures

Decrease Risk from Agricultural Pesticides

In 2003 Decrease adverse risk from agricultural uses from 1995 levels and assure that new pesticides that enter the market are safe for humans and the environment, through ensuring that all registration action are timely and comply with standards mandated by law.

In 2002 Decrease adverse risk from agricultural uses from 1995 levels and assure that new pesticides that enter the market are safe for humans and the environment, through ensuring that all registration actionare timely and

comply with standards mandated by law.

In 2002 Provide timely decisions to the pesticide industry on the registration of active ingredients for conventional pesticides.

In 2001 The Agency registered 9 new chemicals, exceeding its target by 2, and 267 new chemicals, underperforming its target by 83.

In 2001 The registration of new agricultural pesticides, and reregistration of older agricultural pesticides, were done under the strict health-based standard of FQPA: "reasonable certainty of no harm." "Safer" pesticides are those that meet a stricter set of criteria.

Performance Measures:	FY 2001 Actual	FY 2002 Enacted	FY 2003 Request	Units
Register safer chemicals and biopesticides	92	105	118	Regist. (Cum)
New Chemicals	53	60	67	Regist. (Cum)
New Uses	1896	2329	2679	Actions (Cum)

Baseline: The baseline year is 1996; baseline quantities are 0. 1996 is the year FQPA was enacted with its new risk reduction, safety standard "reasonable certainty of no harm" for pesticides used on foods. Cumulative totals measured from baseline for safer chemicals, biopesticides, new chemicals, and new uses are displayed because this more clearly shows progress implementing FQPA than would a display of single-year results.

Reduce use of highly toxic pesticides

In 2003 Occurence of residues of carcinogenic and cholinesterase inhibiting neurotoxic pesticides on foods eaten by children will have decreased by 20 percent (cumulative) from their average 1994 to 1996 levels.

In 2002 Detections of residues of carcinogenic and cholinesterase inhibiting neurotoxic pesticides on foods eaten by children will have decreased by 15 percent (cumulative) from their average 1994 to 1996 levels.

In 2001 Data will be available in March 2002.

Performance Measures:	FY 2001 Actual	FY 2002 Enacted	FY 2003 Request	Units
Reduction of detections on a core set of 19 foods eaten by children relative to detection levels for those foods reported in 1994-1996.		15%	20%	Reduced Detect.

Baseline: Percent occurrence of residues of FQPA priority pesticides (organophosphates and carbamates) on samples of children's foods in baseline years 94-96. Baseline percent is 33.5% of composite sample of children's foods: apples, apple juice, bananas, broccoli, carrots, celery, grapes, green beans (fresh, canned, frozen), lettuce, milk, oranges, peaches, potatoes, spinach, sweet corn (canned and frozen), sweet peas (canned and frozen), sweet potatoes, tomatoes, and wheat.

Reduced Risk Pesticides

In 2003 At least six percent of acre-treatments will use applications of reduced risk pesticides.

In 2002 At least one percent of acre-treatments will use applications of reduced risk pesticides.

Performance Measures:	FY 2001 Actual	FY 2002 Enacted	FY 2003 Request	Units
Percentage of acre treatments with reduced risk pesticides		1%	6%	Acre Treatments

Baseline: Baseline is 1998 acre-treatments: 3.6% of total acreage. Each year's total acre-treatments (all pesticides and reduced risk pesticides), reported by USDA's National Agricultural Statistical Survey (NASS), serve as the basis for computing the percentage of acre-treatments using reduced risk pesticides. Acre-treatments count the total number of pesticide treatments each acre receives each year.

Verification and Validation of Performance Measures

Performance Measures:

- **Number of registrations of reduced risk pesticides.**
- **Percentage of acre treatments with reduced risk pesticides.**
- **Reduction of pesticide detection on foods eaten by children.**

Performance Database**:** Pesticide Regulatory Action Tracking System (PRATS). PRATS is maintained by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and is designed to track regulatory data submissions and studies, organized by scientific discipline, which are submitted by the registrant in support of a pesticide's registration. Additionally, the Program divisions maintain manual counts of the registrations of reduced risk pesticides. The information is provided to the Office Director's immediate office for consolidation and recordkeeping.

Data Source: The Office of Pesticide Programs (OPP) Staff (reviewers)

QA/QC Procedures: A reduced risk pesticide must meet the criteria set forth in Pesticide Registration Notice 97-3, September 4, 1997. Reduced risk pesticides include those which reduce the risks to human health; reduce the risks to non-target organisms; reduce the potential for contamination of groundwater, surface water or other valued environmental resources; and/or broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective. In addition, biopesticides are generally considered safer (and thus reduced risk).

Data Quality Review: Management reviews the program counts and signs off on the decision document which is then forwarded to the Office Director.

Data Limitations: None. All required data must be submitted for the risk assessments before the pesticide, including a reduced risk pesticide, is registered. If data are not submitted, the pesticide is not registered. A reduced risk pesticide must meet the criteria set forth in PRN 97-3. If it does not meet the criteria, it is not reviewed as a reduced risk, but as a conventional active ingredient. All risk assessments are subject to public and scientific peer review.

New/Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) consolidates various OPP program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003.

Statutory Authorities

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)
Federal Food, Drug and Cosmetic Act (FFDCA)
Food Quality Protection Act (FQPA) of 1996

Objective 2: Eliminate Use on Food of Pesticides Not Meeting Standards

By 2008, use on food of current pesticides that do not meet the new statutory standard of "reasonable certainty of no harm" will be eliminated.

Key Program

(Dollars in Thousands)

	FY 2001 Enacted	FY 2002 Enacted	FY 2003 Request	FY 2003 Req. v. FY 2002 Ena.
Administrative Services	$279.5	$0.0	$0.0	$0.0
Endocrine Disruptor Screening Program	$3,457.0	$3,388.7	$3,264.1	($124.6)
Facilities Infrastructure and Operations	$6,354.9	$4,575.2	$5,154.0	$578.8
Homeland Security	$0.0	$876.8	$0.0	($876.8)
Legal Services	$372.3	$433.5	$465.5	$32.0
Management Services and Stewardship	$860.0	$931.5	$854.6	($76.9)
Pesticide Reregistration	$27,621.2	$27,170.8	$38,592.4	$11,421.6
Pesticide Residue Tolerance Reassessments	$13,616.1	$13,858.5	$4,607.9	($9,250.6)
Research to Support FQPA	$10,905.5	$11,377.4	$10,821.3	($556.1)
Science Coordination and Policy	$275.8	$315.1	$764.4	$449.3

Annual Performance Goals and Measures

Reassess Pesticide Tolerances

In 2003 Assure that pesticides active ingredients registered prior to 1984 and the products that contain them are reviewed to assure adequate protection forhuman health and the environment.Also consider the unique exposure scenarios such as subsistence lifestyles of Native Americans in regulatory decisions.

In 2003 By the end of 2003 EPA will reassess a cumulative 68% of the 9,721 pesticide tolerances required to be reassessed over ten years and complete reassessment of a cumualtive 75% of tolerances of special concern

in protecting the health of children.

In 2002 Assure that pesticides active ingredients registered prior to 1984 and the products that contain them are reviewed to assure adequate protection forhuman health and the environment.Also consider the unique exposure scenarios such as subsistence lifestyles of Native Americans in regulatory decisions.

In 2002 By the end of 2002 EPA will reassess a cumulative 66% of the 9,721 pesticide tolerances required to be reassessed over ten years. This includes 67% of the 893 tolerances having the greatest potential impact on dietary risks to children.

In 2001 EPA reassessed 40% of tolerances requiring reassessment under FQPA and issued a cumulative 72% of total REDs required, achieving both targets.

In 2001 EPA reregistered 856 products, exceeding its target by 14%.

Performance Measures:	**FY 2001 Actual**	**FY 2002 Enacted**	**FY 2003 Request**	**Units**
Tolerance Reassessment	40%	66%	68%	Tolerances(Cum)
REDs	71.6%	76.4%	83%	Decisions (Cum)
Product Reregistration	856	750	750	Actions
Tolerance reassessments for top 20 foods eaten by children	43.5%	67%	75%	Tolerances(Cum)

Baseline: The baseline value for tolerance reassessments is 9,721 tolerances that must be reassessed using FQPA health and safety standards; REDs is 612 REDs that must be completed; product reregistration is under development; and tolerances reassessed for the top 20 foods eaten by children is 893. Cumulative totals for tolerances reassessed and REDs are displayed because this more clearly shows progress in implementing FQPA than would a display of single-year results shown in earlier years.

Verification and Validation of Performance Measures

Performance Measures:

- **Number of tolerance reassessments**
- **Number of REDs**
- **Number of Product Reregistrations**

Performance Database: Tolerance Reassessment Tracking System (TORTS) is an in-house (Office of Pesticide Programs-wide) system containing records on all 9,721 tolerances subject to reassessment. It contains numbers of total tolerances reassessed; breakout by Fiscal Year, source, & priority group; outcomes of reassessments (number of tolerance levels raised, lowered, revoked, remaining same). It also provides counts of tolerances reassessed for organophosphates, carbamates, organochlorines, carcinogens and high hazard inerts, children's foods, and minor uses.

Data Source: Office of Pesticide Programs (OPP) Staff (reviewers)

QA/QC Procedures: OPP Management verifies/signs decision to count tolerance as reassessed or not, as a result of the Reregistration Eligibility Decision or decision to approve registration. Additionally, the Program Divisions maintain counts of the tolerances reassessed. The information is provided to the Office Director's immediate office for consolidation and record-keeping.

Data Quality Review: Management reviews the program output counts. Tolerance counting rules are reviewed for consistency across the programs. Decisions are made by management as to whether the tolerance requires cumulative risk assessment or individual risk assessment. This decision is made based on whether the tolerance belongs to a group of chemicals which have a common mode of toxicity.

Data Limitations: Because the measure is a numeric count, there are no data limitations. Data needed for registration or reregistration/tolerance reassessment are provided by the pesticide registrant. If the data required for the risk assessment is not provided with the original package, then the information is requested from the registrant. The pesticide is not registered or reregistered until the required data are submitted. Should the registrant choose not to support a reregistration and associated tolerance reassessments, the Agency may cancel the pesticide involved.

New / Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) database consolidates various OPP program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003. **Number of registrations of reduced risk pesticides.**

Performance Database: Pesticide Regulatory Action Tracking System (PRATS). PRATS is maintained by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and is designed to track regulatory data submissions and studies, organized by scientific discipline, which are submitted by the registrant in support of a pesticide's registration. Additionally, the Program Divisions maintain manual counts of the registrations of reduced risk pesticides. The information is provided to the Office Director's immediate office for consolidation and recordkeeping.

Data Source: The Office of Pesticide Programs (OPP) Staff (reviewers)

QA/QC Procedures: In order to meet the criteria of a reduced risk pesticide, the pesticide must meet the criteria set forth in PR Notice 97-3, September 4, 1997. Pesticides include those which reduce the risks to human health; reduce the risks to non-target organisms; reduce the potential for contamination of groundwater, surface water or other valued environmental resources; and/or broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective. In addition, biopesticides are generally considered safer (and thus reduced risk).

Data Quality Review: Management reviews the program counts and signs off on the decision document which is then forwarded to the Office Director.

Data Limitations: None. All required data must be submitted for our risk assessments before the pesticide is registered. This applies to reduced risk candidates, as well. If data are not submitted, the pesticide is not registered. A reduced risk pesticide must meet the criteria set forth in PRN 97-3. If it does not meet the criteria, it is not reviewed as a reduced risk, but as a conventional active ingredient. All risk assessments are subject to public and scientific peer review.

New/Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) consolidates various OPP program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003.

Statutory Authorities:

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)
Federal Food, Drug and Cosmetic Act (FFDCA)
Food Quality Protection Act (FQPA) of 1996
Toxic Substances Control Act (TSCA)

Research

Food Quality Protection Act of 1996 (FQPA)
Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
Toxic Substances Control Act (TSCA)
Federal Food, Drug, and Cosmetic Act (FFDCA)